



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,191	07/11/2003	Karl F. Popp	24948	3528
20529	7590	08/31/2006	EXAMINER	
NATH & ASSOCIATES 112 South West Street Alexandria, VA 22314			CHANNAVAJALA, LAKSHMI SARADA	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 08/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/617,191	Applicant(s) POPP, KARL F.	
	Examiner Lakshmi S. Channavajjala	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10-10-03;3-30-06</u> & <u>10-1-04</u> | 6) <input type="checkbox"/> Other: ____. |

Art Unit: 1615

DETAILED ACTION

Receipt of IDS dated 10-10-03 and 3-30-06 is acknowledged.

Claims 1-35 are pending in the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11, 14-26 and 30-34 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,117,843 to Broody et al (Broody).

Instant claims are directed to a composition, a method of preparing the composition and a method of treatment, wherein the composition comprises a storage-stable mixture of benzoyl peroxide dispersion, clindamycin and a pharmaceutically acceptable carrier, before mixing and a final pH of 4.5 to 5.0.

Broody discloses a composition comprising clindamycin, benzoyl peroxide and a carrier, for the treatment of acne, which is stable for several months (col. 2, L 3-66).

Broody discloses incorporating clindamycin salt that is compatible with the gelling agent and a dispersion of finely divided benzoyl peroxide, wherein the dispersion and clindamycin are combine with a carrier, and further with a gelling agent such as

Art Unit: 1615

Carbopol (col. 4, L 1-43). Table 1 of Broody shows final composition, which contains the claimed amounts of benzoyl peroxide and clindamycin, and has a pH of 4.5-5.5, which includes the pH of the instant claims. Thus, Broody discloses the composition for the same purpose claimed in the instant application (claims 17-25, in particular claim 22 of the instant application). For claims 2 & 3, Broody discloses applying the composition once or twice daily (col. 7, L 25-35). For claimed stability (claims 7-8), Broody shows that the composition is stable over a long period of time (table 7 and 8). For claims 23-25, Broody does not specify the age group of patients that are treated with the composition. However, the examples show that the composition is highly effective against acne (col. 15-16) and therefore the composition of Broody is effective against all the age groups (including those claimed). With respect to the viscosity, Broody discloses that initial viscosity of benzoyl peroxide in the range of 50,000 to 90,000 and a final viscosity in the range of 70,000 to 120,000. For claim 13, instant claims are directed to a final product i.e., composition and broody teaches the viscosity of the composition having a final viscosity that overlaps with the claimed viscosity. Thus, the composition of Broody possesses viscosity in the same range as in the instant composition and thus, anticipates instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 1615

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13, 27-29 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,117,843 to Broody et al (Broody).


Broody does not teach the purity of benzoyl peroxide, viscosity of benzoyl peroxide of claim 13, the percentage degradation of clindamycin or the amounts of benzoyl peroxide and clindamycin in the claimed standard deviation. However, Broody also recognize the same factors i.e., pH, viscosity etc., that affect the stability (result-affective variables) of the composition and therefore it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to employ pure active compounds and optimize the general conditions such as viscosity, amounts of active agents with an expectation to achieve a composition that stable for long periods of time because the teachings of Broody are also directed to preparing a storage stable composition comprising benzoyl peroxide and clindamycin and employed for the same purpose similar to the instant invention i.e., treatment of acne or other skin related conditions that need require benzoyl peroxide and clindamycin combination. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

Art Unit: 1615

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala
Examiner
Art Unit 1615
August 28, 2006